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10. SUMMARY OF 510(k)

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is ___K063673_____.

Submitter:

Innovacon, Inc.
4106 Sorrento Valley Boulevard
San Diego, California 92121
Tel.: 858-535-2030
Fax: 858-535-2038

Establishment Registration Number: 3005689981
Owner/Operator Number: 9006731

Date:

11/20/06

Contact Person:

Edward Tung, Ph.D.

Product Name:

Innovacon Flipcard™ Fecal Occult Blood Test Device

Common Name:

Fecal Occult Blood Rapid Test

Classification Information:

The Innovacon Flipcard™ Fecal Occult Blood Test Device is similar to other FDA-cleared devices for the qualitative detection of lower gastrointestinal (GI) bleeding that may be related to iron deficiency anemia, peptic ulcer, ulcerative colitis, polyp and colorectal cancer.

Classification:	Class II
Regulation Number:	864.6550
Product Code:	KHE
Classification Name:	Reagent Occult Blood
Complexity:	Waived
Analyte:	Fecal Occult Blood
Test Category:	Manual procedures with limited steps and limited sample and reagent preparation

Intended Use:

The Innovacon Flipcard™ Fecal Occult Blood Test Device is intended for rapid qualitative detection of human hemoglobin in fecal samples. Fecal occult blood tests are used as a screening tool for detecting lower gastrointestinal (GI) bleeding that may be related to iron deficiency anemia, peptic ulcer, ulcerative colitis, polyp and colorectal cancer. The Flipcard™ FOBT is recommended for use by health professionals in routine physical examinations and in monitoring for GI bleeding in patients in hospitals or at physician's offices.

Description:

The Innovacon Flipcard™ Fecal Occult Blood Test Device is a rapid test intended for the qualitative detection of low levels Fecal Occult Blood. The test uses monoclonal antibodies to selectively detect human hemoglobin in fecal samples The test uses a double antibody sandwich assay to selectively detect Fecal Occult Blood at 50 ng hHb/mL buffer or 300 ug hHB/g feces. The FOB One Step Fecal Occult Blood Test does not require the patient to follow any special dietary restrictions.

Comparison to Predicate Devices:

A summary of comparison of the features of the Innovacon Flipcard™ Fecal Occult Blood Test Device, and the predicate device is shown below:

Table 2. Innovacon Flipcard™ Fecal Occult Blood Test Device versus Hemoccult® ICT Immunological Fecal Occult Blood Test

Feature	Innovacon Flipcard™ Fecal Occult Blood Test Device	Hemoccult® ICT Immunological Fecal Occult Blood Test
Indication for use	A lateral-flow immunoassay intended for the qualitative detection of human hemoglobin in fecal samples	A rapid visually read qualitative immunochemical chromatographic method for detection of human hemoglobin in fecal samples.
Intended Use	Professional	Professional
Intended specimen	Fecal	Fecal
Endpoint	Colored Lines	Colored Lines
Materials provided	Flushable Collection Tissues Collection Cards Collection Sticks Protective Pouches Mailing Envelopes Kit Bags w/Patient Instructions FOB Test Devices Buffer Positive Control Negative Control Package insert Procedure card	Test devices Buffer Package Insert
Methodology	Membrane particle assay	Membrane particle assay
Test Time	5 minutes	5 minutes
Format	Antigen/antibody immunoassay	Antigen/antibody immunoassay

Accuracy

A clinical evaluation was conducted using a total of 120 clinical specimens. The detection of human occult blood in clinical fecal specimens was done by using the Innovacon Fecal™ Occult Blood Test Device and Predicate Device, Hemoccult® ICT Immunological Fecal Occult Blood Test

Innovacon Flipcard™ Fecal Occult Blood Test Device compared to Hemoccult® ICT Immunological Fecal Occult Blood Test

Part A Sample Collection from Study Participants

Positive Agreement=2/2 = 100%
Negative Agreement = 115/116 =99.1% (95.3%-100%, 95% CI)
Overall Agreement = 117/118 = 99.2% (95.4%-100%, 95% CI)

Part B Laboratory Study by Professionals

Positive Agreement=46/48 = 95.8% (85.7%-100%, 95% CI)
Negative Agreement = 100/102 =98.0% (93.1%-99.8%, 95% CI)
Overall Agreement = 146/150 = 97.3% (93.3%-99.3%, 95% CI)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

INNOVACON, INC.
C/O Edward Tung
4106 Sorrento Valley Blvd.
San Diego, California 92121

MAR 0 5 2007

Re: k063673
Trade/Device Name: Innovacon Flipcard™ Fecal Occult Blood Test Device
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: KHE
Dated: December 6, 2006
Received: December 11, 2006

Dear Dr. Tung:
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

9. INDICATIONS FOR USE

510(k) Number (if known): K063673

Device Name: Innovacon Flipcard™ Fecal Occult Blood Test Device

Indications For Use: The Innovacon Flipcard™ Fecal Occult Blood Test Device is intended for rapid qualitative detection of human hemoglobin in fecal samples. Fecal occult blood tests are used as a screening tool for detecting lower gastrointestinal (GI) bleeding that may be related to iron deficiency anemia, peptic ulcer, ulcerative colitis, polyp and colorectal cancer. The Flipcard™ FOBT is recommended for use by health professionals in routine physical examinations and in monitoring for GI bleeding in patients in hospitals or at physician's offices.

Prescription Use___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Sign-Off

of In Vitro Diagnostic Device

510(k) K063673